

REMARKS/ARGUMENTS

STATUS OF THE CLAIMS

Claims 1-120 are pending. Applicant has amended Claims 2, 5, 10, 12, 22, 25, 29-35, 37-38, 41, 43, 46-47, 50, 62, 74, 82, 86, 94, 98, 106, 110, and 118. In light of the following, Applicant respectfully requests reconsideration and allowance of the pending claims.

CLAIM REJECTION – 35 U.S.C. § 102

Independent Claim 1

Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,263,480 issued to Wernicke et al. (“Wernicke”).

Claim 1 specifies a “a first electrode positioned within the esophagus of said patient; a second electrode positioned within the esophagus of said patient in spaced apart relation to said first electrode; and means operatively associated with said first and second electrodes for actuating at least one of said electrodes to create an electrical field effective to stimulate said vagus nerve.”

Wernicke discloses a system for treating patients with compulsive eating disorders. *Wernicke*, Abstract. As shown in Figure 2 of Wernicke, the system includes a stimulus generator 10, sensing electrodes 12, a lead assembly 38, stimulation electrodes 40, an electrical connector 65, and a housing 70. Figure 2 of Wernicke also illustrates the patient’s esophagus 14, stomach 13, and vagus nerve 44. Wernicke discloses using both the sensing electrodes 12 and the stimulation electrodes 40 because “it is desirable to employ quadripolar electrodes in which one pair is used for signal generation and the other pair is used for signal sensing.” *Id.* at col. 8, lines 48-51.

Wernicke discloses that the sensing electrodes 12 are preferably secured to opposite sides of the patient’s esophagus 14 at a site just above the stomach 13. *Id.* at col. 8, lines 36-39. As

shown in Figure 3 of Wernicke, a pulsed signal from a pulse generator 15 is applied to the sensing electrodes 12-1, 12-2 via high impedance 17 and leads 20. *Id.* at col. 10, lines 35-41. The amplitude of the signal on sensing electrodes 12 is “a function of the impedance between them, which varies according to whether the esophagus 14 is empty or has food passing through it (and therefore between the electrodes).” *Id.* If the sensing electrodes 12 of Wernicke are the “first electrode” and “second electrode” of Claim 1, the sensing electrodes 12 are not capable of creating an electrical field effective to stimulate the vagus nerve, because Wernicke only discloses that the sensing electrodes 12 determine whether food is passing through the esophagus 14.

Wernicke discloses that the stimulation electrodes 40 are “secured to the patient’s vagus nerve 44 (FIG. 3, and in greater detail in FIG. 4).” *Id.* at col. 9, lines 19-21. Specifically, Wernicke discloses as follows:

Output section 36 and the programmed output signal thereof is coupled (directly, capacitively, or inductively) to an electrical connector 65 on the housing 70 of the generator and to the lead assembly 38 and the stimulating electrodes 40 connected thereto (FIG. 2). In this way, the programmed output signal of stimulus generator 10 is applied to the nerve electrode set implanted on the patient’s vagus nerve 44, to modulate the vagal activity in a desired manner to alleviate the disorder.

Id. at col. 10, lines 5-15.

Wernicke further discloses that the stimulation electrodes 40 are wrapped around the vagus nerve 44, as shown in Figure 4. More specifically, Wernicke discloses as follows:

The electrode assembly is surgically implanted around the vagus nerve 44 in the patient’s abdomen just above the stomach. The two electrodes 40-1 and 40-2 are wrapped about the vagus nerve, and the assembly is secured to the nerve by a spiral anchoring tether 74....

Id. at col. 12, lines 23-28.

If the stimulation electrodes 40 of Wernicke are the “first electrode” and “second electrode” of Claim 1, the stimulation electrodes 40 cannot be positioned within the esophagus of

the patient, because Wernicke discloses that the stimulation electrodes 40 are wrapped around the vagus nerve 44.

In light of the above, Wernicke does not disclose “a first electrode positioned within the esophagus of said patient; a second electrode positioned within the esophagus of said patient in spaced apart relation to said first electrode; and means operatively associated with said first and second electrodes for actuating at least one of said electrodes to create an electrical field effective to stimulate said vagus nerve.” Accordingly, independent Claim 1 and dependent Claims 3, 4, and 7-11 are allowable.

Dependent Claims 3, 4, and 7-11

Claims 3, 4, and 7-11 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Wernicke. Claims 3, 4, and 7-11 depend from Claim 1 and are therefore allowable for the reasons set forth above with respect to Claim 1. Claims 3, 4, and 7-11 also specify additional patentable subject matter not specifically discussed herein.

CLAIM REJECTION – 35 U.S.C. §§ 102 AND 103

Independent Claims 25 and 37

Claims 25 and 37 stand rejected under 35 U.S.C. § 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,792,187 issued to Adams (“Adams”).

Amended Claims 25 and 37 specify “means operatively associated with said first and second electrodes for actuating at least one of said electrodes to create an electrical field effective to stimulate said vagus nerve to achieve controlled asystole.”

Adams discloses a pain control system 10 that uses vagus nerve stimulation during cardioversion/defibrillation. *Adams*, col. 4, lines 24-26. Adams does not disclose, teach, or

suggest stimulating the vagus nerve to achieve controlled asystole. Accordingly, independent Claims 25 and 37 and dependent Claims 26-28 and 38-40 are allowable.

Dependent Claims 26-28 and 38-40

Claims 26-28 and 38-40 stand rejected under 35 U.S.C. § 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over Adams. Claims 26-28 and 36-40 depend from Claims 25 and 37, respectively, and are therefore allowable for the reasons set forth above with respect to Claims 25 and 37. Claims 26-28 and 36-40 also specify additional patentable subject matter not specifically discussed herein.

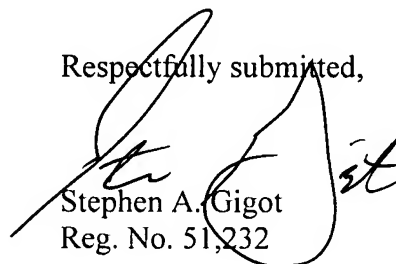
ALLOWABLE SUBJECT MATTER

Applicant appreciates the indication of allowable subject matter in Claims 2, 5, 6, 12, 29-36, and 41-48, and the allowance of Claims 13-24 and 49-120. Applicant has amended Claims 2, 5, 12, 29, 31, 34, 35, 41, 43, 46, and 47 into independent form. Applicant has amended new independent Claims 34 and 46 to specify a pulse duration of at least 0.1 msec. Applicant respectfully requests that the Examiner allow Claims 34 and 46 as amended.

CONCLUSION

In light of the above, Applicant respectfully requests reconsideration and allowance of pending Claims 1-120.

Respectfully submitted,



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